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Agricultural Biotechnology Research Advisory Committee

December 3-4, 1991

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U.S. DEPARTMENT OF AGRICULTURE
Agricultural Biotechnology Research Advisory Committee
Minutes of Meeting
December 3-4, 1991

Time, Place, and Participants

A meeting of the Agricultural Biotechnology Research Advisory Committee (ABRAC) took place on December 3 and 4, 1991, in the Cabinet Room of the Governors' House Holiday Inn at 17th Street and Rhode Island Avenue, N.W., Washington, DC. The meeting had been announced in the ***Federal Register*** and was open to the public.

Members present included:

Bennie Osburn, Chair, University of California, Davis, CA;
A. Ann Sorensen, American Farm Bureau Federation, Park Ridge, IL;
Lee Bulla, University of Wyoming, Laramie, WY;
Harold Hafs, Merck, Sharp, & Dohme Laboratories, Rahway, NJ;
William Witt, Food and Drug Administration, National Center for Toxicological Research, Jefferson, AR;
Hugh Bollinger, TerraTek, Inc., Salt Lake City, UT;
Frank Whitmore, Ohio State University, Wooster, OH;
Sue Tolin, Virginia Polytechnic Institute and State University, Blacksburg, VA;
John Kemp, New Mexico State University, Las Cruces, NM;
Edward Korwek, Hogan and Hartson, Washington, DC;
Anne Vidaver, University of Nebraska, Lincoln, NE;
Deborah Letourneau, University of California, Santa Cruz, CA;
David Andow, University of Minnesota, St. Paul, MN;
A. David Kline, State University of New York at New Paltz, New Paltz, NY;
Alvin Young, Executive Secretary, ABRAC, and Director, Office of Agricultural Biotechnology, U.S. Department of Agriculture, Washington, DC.

U.S. Department of Agriculture (USDA) Office of Agricultural Biotechnology (OAB) staff present included Daniel Jones, Maryln Cordle, Marti Asner, and Barry Stone. Others present are listed in Appendix A.

Call to Order and Preliminaries

Dr. Osburn called the meeting to order at 9:10 a.m. He welcomed the ABRAC members, OAB staff, and guests, and asked the guests to introduce themselves.

Dr. Osburn specified three objectives for this meeting:
1) Finish work on the ***Proposed Guidelines for Research Involving Planned Introduction into the Environment of Genetically Modified Organisms*** (henceforth referred to as the Guidelines);
2) Discuss a mechanism for publishing the Guidelines; and
3) Discuss a justification for the Guidelines to be included in the preamble.

Dr. Osburn then asked Lisa Zannoni, Office of the Secretary, USDA, to update the ABRAC on the implementation of the Guidelines.

Update on Implementation of the Guidelines

Ms. Zannoni told the ABRAC that little had happened regarding implementation since the previous ABRAC meeting in May, 1991. She said that all USDA agencies affected by the Guidelines had been directed to complete implementation plans by the end of December. In addition, the Forest Service and Agricultural Research Service (ARS) were being asked to draft models of policy manuals for their implementation of the Guidelines.

Ms. Zannoni said that all of the implementation plans would proceed through the USDA clearance process during January. In response to a question from Dr. Andow, she replied that the clearance process for the Cooperative State Research Service (CSRS) would be the most extensive.

Dr. Osburn asked how implementation would be handled in the ***Federal Register***. Ms. Zannoni said that three notices would be published: one for the Guidelines; one consisting of amendments to USDA regulations regarding grants; and one for amendments to specific USDA agency regulations.

Dr. Osburn asked if the Guidelines would include both scope and implementation. Ms. Zannoni responded that scope would have to be included. She noted the Biotechnology Working Group of the Council on Competitiveness currently lacks a chairman, but that scope would be considered when a new chairman is named. An

additional incentive to resolve the scope issues, she said, is that the U.S. Environmental Protection Agency (EPA) is submitting its regulations implementing the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for Administration review.

Ms. Zannoni noted that the Office of Management and Budget (OMB) now views the Institutional Biosafety Committees (IBC's) more favorably than it had previously.

Dr. Bollinger cited a recent newspaper article on the activities of the Council on Competitiveness, and asked if the Council was happy with the current thinking on the product-vs.-process issue. Ms. Zannoni cited a recent report from the Congressional Office of Technology Assessment (OTA) which stated that, realistically speaking, process cannot be divorced from scope. In any case, she added, USDA still backs the scope exclusions; without such exclusions, the work of the IBC's would bog down.

Dr. Kemp asked Ms. Zannoni to detail the role of the IBC's. Ms. Zannoni replied that the ABRAC's advice on IBC performance standards had been used. She stressed that universities need flexibility and that IBC performance standards would be less of a hindrance to research than design standards.

Dr. Osburn then asked Ms. Cordle to discuss responses to public comments on the Guidelines.

Response to Public Comments

Ms. Cordle noted that some of the public comments on the Guidelines prompted the ABRAC to decide to develop new examples that show not only how to evaluate the safety of a parental organism, but also the safety of the proposed genetic modification, and the safety of the modified organism. She said that little had been done on the preamble to the Guidelines because the ABRAC must make some final decisions on issues pertaining to the Guidelines.

Dr. Young noted that in examining the comments, the OAB staff catalogued and classified material from 72 different commentors, and that each area commented upon must be addressed in the preamble.

Dr. Tolin asked if the preamble focuses mainly on responses to comments, or on the background of the Guidelines. Ms. Cordle responded that in discussing the comments, the preamble must discuss the need for the Guidelines.

Dr. MacKenzie asked if the Guidelines would be subject to another round of public comments. Ms. Cordle replied that USDA's Office of General Counsel (OGC) would make that decision. She noted

that the ABRAC has strongly recommended that the Guidelines be reopened for comment.

Dr. Andow asked what kind of clearance would be needed if the ABRAC published the Guidelines on its own. Dr. Young replied options include publishing the document as part of the advisory committee process, or submitting the Guidelines for publication in a scientific journal.

Ms. Zannoni said that the Assistant Secretary for Science and Education is strongly committed to implementing the Guidelines. Dr. Young said that there is some concern that despite such support, implementation may not occur -- for example, if the scope issue is not resolved.

Ms. Zannoni cautioned that once the Guidelines are sent to OMB for clearance, they cannot be published independently, because such publication would be considered a breach of confidence. She advised the OAB to consult with OGC on the matter. Dr. Young did so, and later reported that OGC said private publication of the Guidelines would not be illegal, but publication should be under the aegis of individuals, not the ABRAC. Dr. Young inferred that OGC does not consider publication of the Guidelines to be part of ABRAC's role.

Dr. Bulla asked when implementation would occur. Ms. Cordle responded that the preamble would take two months to complete. Ms. Zannoni noted that OMB must clear the Guidelines, and that the scope issue must be resolved. She said she hoped the Guidelines would be published in six months.

Dr. Bulla suggested that the ABRAC not pursue private publication at present. Eventually, if publication did not occur, an article summarizing the Guidelines could be submitted as an editorial. Ms. Zannoni indicated that a publication of a summary of the Guidelines while the clearance process was underway would be permissible.

Dr. Young noted that the next full ABRAC meeting is scheduled for February 19-21, 1992, and that if the Guidelines are finished before that time, the current ABRAC chair could approve them. He suggested that the completed Guidelines include a cover letter or letter of transmittal from the Chair to the Assistant Secretary.

Ms. Cordle said that if the ABRAC decides to pursue such a course, someone would need to write a preface to the Guidelines. Dr. Tolin said that the preface could be part of the cover letter; Dr. Bulla suggested that it be included in the minutes.

Dr. Bulla also recommended that the preface include a list of earlier ABRAC members, as well as consultants such as Marshall Phillips, and the OAB staff.

Dr. MacKenzie questioned whether the examples should be included in the ***Federal Register***, or issued as a separate handbook. He suggested that the ABRAC simply give the Guidelines and the cover letter without examples to the Assistant Secretary. Ms. Cordle replied that the handbook idea had been considered, but that the Guidelines were so general that interpretation would be difficult without examples to accompany them. Dr. Young said that OGC would decide what the Guidelines package should include, and he cautioned that rushing an incomplete package to the Assistant Secretary would cause problems later.

Dr. Osburn asked Dr. Bulla to meet with Drs. Tolin and Kemp to consider how the Guidelines should be published, and to draft an appropriate resolution. Dr. Korwek cautioned against drafting a resolution in the face of speculation about possible outcomes.

Dr. Osburn invited Dr. Kemp to report on the work of the Classification and Confinement Working Group.

Update on Classification and Confinement Working Group

Dr. Kemp recounted the history of the Classification and Confinement Working Group (henceforth referred to as the Working Group). At its first meeting, which was held May 21, 1991, the Working Group compressed the number of levels of safety concern in the Guidelines from five to three, and reworked the examples. At a later meeting, held October 30 and 31, 1991, the Working Group expanded the examples to include not only the parental organism, but also the proposed genetic modification, and the modified organism. Finally, at a meeting on December 2, 1991, the Working Group conducted a section-by-section review of the Guidelines and made further changes.

Dr. Kemp reported that the Working Group had taken the entire day to review the Guidelines to ensure that all of the members concurred with the draft to be presented to the full ABRAC. However, because the Working Group had spent the entire day reviewing the Guidelines, it had not been able to review the examples. Dr. Kemp asked that the entire ABRAC review the examples, and that comments be sent to the individual authors of each example, who would then make the necessary modifications before sending the rewritten examples to the OAB.

Ms. Cordle asked that comments be sent to the authors by December 20, and that authors submit their final versions of the examples to the OAB by January 15.

Discussion of the Guidelines

Dr. Kemp then outlined the Working Group's proposed changes to the Guidelines.[1] He then moved that the full ABRAC accept the draft Guidelines with changes as proposed by the Working Group as the final version of the Guidelines. Dr. Bulla seconded the motion.

Dr. Korwek complimented the OAB staff for putting the new draft of the Guidelines together. However, he expressed concern that the Guidelines, by using terms such as "cause" and "may cause," appeared variant. To eliminate these variations, he suggested that language concerning such standards be repeated verbatim throughout the document. Ms. Cordle and the ABRAC members replied that the variant terms were intentional in order to distinguish among the different levels of safety concern in the Guidelines.

Dr. Korwek also expressed concern about the Working Group's proposed changes to Section III-A-3 might conflict with what other groups -- particularly the White House Office of Science and Technology Policy (OSTP) -- would say about scope. Ms. Cordle replied that the Assistant Secretary had told the OAB not to wait for further guidance on scope, but to go ahead and do what it thought best. She added that EPA had engaged in considerable deliberation on microorganisms, and that the OAB wanted to bring those deliberations to the attention of the ABRAC.

Dr. Korwek asked if any final OSTP decisions on scope would pre-empt decisions on scope by the ABRAC. Ms. Cordle replied that OSTP recognizes that particular applications may require different definitions of scope.

Dr. Korwek then turned to Section II-A-12, which defines "research involving planned introduction into the environment." He objected to the phrase "appropriate confinement," asking why the Guidelines would be needed if confinement already was appropriate. Ms. Cordle answered that this section's intent is to distinguish between "planned introduction" into the environment and commercial release. Dr. Korwek pointed out the difficulty in distinguishing between commercial and non-commercial research and the need to be clear about what research activities are included.

Dr. Korwek questioned the definition of safety, pointing out that an acceptable risk may be negligible or significant. With regard

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[1]These changes are detailed in the minutes of the December 2, 1991, meeting of the Agricultural Biotechnology Research Advisory Committee's Classification and Confinement Working Group.

to Section III-B, Dr. Korwek pointed out that the wording suggests that EPA regulates microbial pesticides under the Toxic Substances Control Act (TSCA). Ms. Cordle said she would revise the sentence to clarify that pesticides are regulated under FIFRA.

Dr. Korwek expressed the view that Section III-B was not clear on whether a researcher needs to comply with the Guidelines if he or she has complied with another agency's regulatory requirements.

Ms. Cordle responded that the Guidelines do not address compliance at all, and that compliance would be addressed in the CSRS companion document. Dr. Korwek maintained that Section III-B's references to other Federal agencies gives the Guidelines a mandatory character. Dr. Schechtman suggested that the references be retained for clarification, but that this section be rewritten to include language similar to that of the NIH guidelines.

Dr. Bulla then opened a discussion of Section III-A-3. The discussion centered on whether to remove 3(i) and 3(ii), as recommended by the Working Group. Alternatively, Dr. Bulla also suggested removing 3(iii) and inserting "unmodified" in the beginning phrase of 3(b) to read, "the movement of unmodified nucleic acids using physiological processes..." Those supporting deletion of 3(i) and 3(ii) believe there is no safety concern about the movement of unmodifed DNA by physiological processes, based on extensive experience and familiarity. They also pointed out that it seems illogical to exempt 3(a) and then place these restrictions on 3(b). Those expressing concern about the elimination of 3(i) and 3(ii) pointed out that while these changes may occur in nature, the rate may be different and this could result in unexpected and unintended environmental impact.

Dr. Berkowitz suggested that the last sentence of III-A-4 be used as a qualifier in III-A-3-b as this focuses on the risk concerns and not process.

Dr. Korwek expressed bewilderment with the ABRAC's continued review of the scope issue. He said that no document could cover every eventuality, and that scope questions might have to be handled on a case-by-case basis. He predicted that no matter what the ABRAC decides on scope, someone will challenge that decision.

Dr. Kemp said that the Guidelines need to be a document that scientists believe is consistent and makes sense. He expressed hope that the Guidelines would not penalize those techniques which are designed simply to accelerate natural processes.

Dr. Osburn asked Dr. Andow to meet with Drs. Kemp, Letourneau, Vidaver, and Bulla to develop recommendations for rewording Section III-A-3. The ABRAC then agreed to postpone a vote on Dr. Kemp's motion, and began to consider the examples.

Discussion of Examples

Dr. Kemp noted that the original examples in the Guidelines only dealt with parental organisms, but that public comments had asked that the examples be carried through to the modified organism. In response to those comments, the Working Group had drafted new examples. He then asked each of the authors to highlight the examples that he or she had drafted.

Dr. Hafs summarized the example of *Bos taurus*, domestic cattle. After a brief discussion, Dr. Andow suggested that the references in this example be made consistent.

Dr. Witt summarized the example of *Cyprinus carpio*, scaleless common carp. Ms. Cordle suggested that more information be included on predators and habitat. Dr. Barbossa recommended that the section on ecological relationships with other organisms be expanded to include more than simply other types of carp. Dr. Tolin agreed with Ms. Cordle that more information was needed on area predators. Dr. Sorensen asked whether this example and the other examples should be written in narrative or outline form.

Dr. Sorensen summarized the example of *Cardiochiles nigriceps*, a parasitic wasp. Ms. Cordle said the modification for this example should be rated Type 3, not Type 2. Dr. Andow said that this example shows that the Guidelines do not require the researcher to evaluate adverse relationships, and that Section VI-B-3 should focus on adverse ecological relationships. Dr. Schechtman noted that this example was written amid some uncertainty, and that with new information, the level of safety concern (LSC) could be reassigned. Dr. Barbossa said this was a highly complex example that could have either highly positive or negative effects.

Dr. Whitmore summarized the example of *Pinus taeda*, loblolly pine. He said he might have to change the definition of "accessible environment" in this example to conform with a probable new definition in the Guidelines. He had thought "accessible environment" meant where an organism will grow; however, the Guidelines' new definition (as recommended by the Working Group) deals with the environment the organism can reach. Ms. Cordle asked that Steps 2 and 3 in this example be explained more fully, and questioned the Type 3 designation for the modification.

Dr. Kemp summarized the example of *Brassica napus*, oil rapeseed, which involved the transfer of two marker genes and a seed storage protein gene into the host plant. He pointed out that an isolation distance of 1/4 mile usually is sufficient to keep cross-pollination with undesirable species below 0.05 percent. Dr. Schechtman noted that APHIS had evaluated this experiment, and that this example shows how the principles of the Guidelines can guide an investigator's thinking, even though this example already is being regulated. Dr. Osburn suggested that the examples indicate when they already are being regulated.

Dr. Letourneau expressed concern that the 0.05 percent cross-pollination level may not be low enough to prevent an herbicide resistance gene from moving from a host plant to a weedy relative. Dr. Schechtman pointed out that outcrossed hybrids of the *Brassica* example are infertile.

Dr. Vidaver summarized the example of *Pseudomonas fluorescens*, a soil microorganism. Dr. Hafs asked that this example include a paragraph on confinement recommendations and the rationale for such recommendations. Ms. Cordle asked that a rationale be included for the assignment of Type 2 to the genetic modification. Dr. Andow suggested that a point-by-point summary be prepared for the modified organism, as had been prepared for the parental organism. Dr. Kline felt that this example needed to have a different type of modification in order to make it more interesting and illuminating.

Dr. Vidaver summarized the example of *Clavibacter xyli*, a plant-associated microorganism. She said that the modification in this example should be designated Type 3, not Type 2, because the effects of the modification on this organism are not well known, even though the modification involves a well-characterized toxin. Members engaged in extensive debate over whether the modification should be Type 2 or Type 3. Ms. Cordle said that if the modification were Type 3, a rationale must be included. Both Dr. Tolin and Ms. Cordle said that the modified organism would be an LSC-2, despite the Type 3 modification.

Dr. Letourneau summarized the example of *Drosophila melanogaster*, a fruit fly, with a genetic modification for temperature-independent sterility. Dr. Kemp explored the scenario of a temperature drop and possible movement of the sterility gene into the general fly population.

Dr. Osburn asked that comments be sent directly to the authors of the examples, unless such comments were minimal. Dr. Tolin volunteered to write an example dealing with a soybean mosaic virus, and Ms. Cordle asked that such an example include a Type 3 modification. Dr. Osburn suggested that the examples take either narrative or outline form, but that they follow the points raised in the Guidelines.

ABRAC members agreed not to use numbers to rate the individual attributes of the parental organism, but rather to characterize the safety concern as low, moderate, or high. Dr. Vidaver suggested that each example include the objectives of the proposed experiment.

Dr. Osburn recessed the meeting at 5:25 p.m.

December 4, 1991

Dr. Osburn reconvened the meeting at 9:15 a.m.

Dr. Kemp moved that the ABRAC approve the examples as corrected. Dr. Sorensen seconded the motion, and the motion passed unanimously.

Dr. Kemp then asked the ABRAC to consider preparing a justification for the Guidelines to be used in the preamble.

Discussion of Justification for the Guidelines

Ms. Cordle explained that the preamble to the Guidelines must state the purpose of the Guidelines and why they are needed. She noted that the public comments were mixed in this regard; many supported the Guidelines, but others felt that current regulations provide sufficient oversight.

Ms. Cordle went on to say that the preamble must include two components: (1) points to consider; and (2) the need for an oversight feature. She also said the Guidelines must address why the Guidelines do not deal with naturally occurring, indigenous organisms, or with non-indigenous, exotic organisms. To deal with indigenous organisms, Ms. Cordle suggested that the preamble stress familiarity; with regard to non-indigenous organisms, the preamble could note that many laws and regulations already deal with such organisms.

Dr. Hafs said that ABRAC was not told to deal with either type of organism in preparing the Guidelines. Dr. Kemp said that the purview of the Guidelines is genetically modified organisms. Dr. Tolin suggested that use of Step 1 of the Guidelines could help deal with this issue.

After some discussion, Ms. Cordle suggested that the Guidelines acknowledge that its principles could be appropriate when dealing with the indigenous and non-indigenous organisms, but that USDA has chosen not to address such organisms directly. She also suggested that the Guidelines point out that new techniques

enable certain processes to be performed with greater precision, and that the Guidelines help researchers to use information from these processes to achieve greater safety and aid in evaluations.

Dr. Young asked Dr. Schechtman how APHIS was addressing new techniques, organisms, and products not covered under current regulations -- for example, transgenic fish. Dr. Schechtman responded as follows:

- A direct plant/pest component in a genetic construct of a modified plant prompts an examination by APHIS in terms of risk.
- If APHIS has reason to believe that a plant has become a pest, it will examine such a plant.
- A direct plant/pest component in a genetically modified organism prompts examination by APHIS.

Ms. Cordle asked what APHIS would do in the case of a gene that is shot into a plant with a particle gun. Dr. Schechtman said his understanding is that such cases generally are not regulated.

Dr. Tolin reminded the ABRAC that many of the examples in the Guidelines already are being regulated, and cautioned the ABRAC to be careful about using the concept of prior regulation as a rationale for what the Guidelines cover.

Dr. Kline said that part of the Guidelines' purpose is to give the public more confidence in a whole range of technologies. Ms. Cordle said that OMB is critical of that argument as a justification for the Guidelines.

Dr. Bollinger suggested that the contingencies outlined in Section III-A-4 of the Guidelines be stated in the preamble.

Ms. Cordle asked the ABRAC to consider how to deal with some public comments that current regulations provide sufficient oversight with regard to experiments involving genetically modified organisms. Dr. Kemp said that the Guidelines are designed to cover all perceived safety problems, not just the plant/pest risks covered by APHIS.

Dr. Bulla said that these questions should be decided by the Secretary and Assistant Secretary. Dr. Young said that former Assistant Secretary Hess had decided on implementation, and that the new Assistant Secretary might well revisit that decision.

Dr. Tolin said that the ABRAC could not resolve these questions. She said that the Guidelines give investigators an overall framework in which to evaluate proposed experiments.

Dr. Kline said the prospect of biotechnology experiments not covered by regulation raised questions of risks in the minds of many people. He said that if no such experiments exist, the Guidelines should be abandoned; if there are such examples besides transgenic fish, they should be mentioned. Dr. Osburn offered biolistics as an example, and suggested that the members of the ABRAC give other examples to Ms. Cordle.

Dr. Osburn then asked Dr. Andow to discuss the work that his discussion group had done on Scope, specifically Section III-A-3(b).

Discussion of Section III-A-3(b)

Dr. Andow reported that his discussion group had come up with two suggestions on how to rewrite Section III-A-3(b). The first suggestion (Option A), consisted of Dr. Kemp's Working Group's recommendation along with Parts (i), (ii), and (iii) from Section III-A-4 and read as follows:

> (b) The movement of nucleic acids using the physiological processes including, but not limited to, transduction, transformation, or conjugation, provided that there has been no directed addition to or rearrangement of nucleic acids from the nucleotide sequences that are moved. This exclusion does not apply if the microorganism is deliberately modified to have (i) increased virulence or toxin production, (ii) significant changes in competitive ability or environmental requirements, or (iii) phenotypic properties that are harmful to humans or would adversely alter the environment.

Dr. Andow then offered an amendment to Dr. Kemp's motion. He moved that the Guidelines be revised to include the definition of scope as specified in Option A. Dr. Bulla seconded the motion.

Dr. Andow then presented the discussion groups's second suggestion for Section III-A-3(b), Option B, which consists of Dr. Kemp's Working Group recommendation along with Part (iii) from Section III-A-4 and read as follows:

> (b) The movement of nucleic acids using the physiological processes including, but not limited to, transduction, transformation, or conjugation, provided that there has been no directed addition to or rearrangement of nucleic acids from the nucleotide sequences that are moved. This exclusion does not apply if the microorganism is deliberately modified to have phenotypic properties that are harmful to humans or would adversely alter the environment.

Dr. Andow noted that a majority of his discussion group preferred Option A to Option B.

Dr. Kemp said that Option B was designed to help the scientist who is engaging in known, familiar processes. He said that he favored Option B.

Dr. Vidaver asked if there were a way to rewrite this section so that it deals with beneficial organisms. Dr. Sorensen suggested the sentence be revised to read, "This exclusion does not apply if the cellular microorganism is deliberately modified to have increased virulence or toxin production, or significant changes in competitive ability or environmental requirements which are harmful to humans or would adversely alter the environment."

The ABRAC voted on Dr. Andow's motion to revise Section III-A-3 as written in Option A. The motion was defeated by a vote of 5-8.

Dr. Andow then moved that the Section III-A-3 be revised as specified in Option B. Dr. Bulla seconded the motion. The motion was defeated unanimously.

Further Changes to and Approval of the Guidelines

Dr. Andow moved that Dr. Kemp's motion be amended to delete from the Guidelines Section III-A-6 (on the grounds that it is redundant), and III-A-7. Dr. Tolin seconded the motion. The motion passed unanimously.

Dr. Andow expressed the view that the intent of the Guidelines' discussion of "accessible environment" needed clarification. He asked whether the term "organism" was being used to mean the parental organism, the parental organism plus offspring at the site of release, or the parental organism and offspring at any location. Dr. Kemp suggested that the phrase "and its progeny in the accessible environment" be added to Section VI-B-1-b, while Dr. Hafs suggested that a population component be added to the Section II-A-10 (the definition of "parental organism").

Dr. Andow moved that the definition of accessible environment (Section II-A-1) be rewritten as follows:

> II-A-1. "Accessible environment" means the environment that can be reached by the introduced organisms or their progeny."

The motion was not seconded, and did not receive further discussion.

Dr. Tolin suggested and ABRAC agreed to add the phrase, "and its progeny" after "organism" in the definition of accessible environment and make the corresponding change at the end of Section VI-A.

The ABRAC agreed to add the phrase "and its progeny" at the end of Section VI-A.

Dr. Osburn called for the question with regard to Dr. Kemp's motion to accept the revised Guidelines as presented by the Working Group on Classification and Confinement, as amended, as the final version of the Guidelines. The motion passed 11-2, with two members absent.

Dr. Hafs asked if the two negative votes would prevent the Guidelines from appearing in the ***Federal Register***. Dr. Tolin said that those who wished to do so could file a minority report.

Dr. Osburn recommended that the Guidelines be published as a document that is separate from the minutes of this meeting, and that the Guidelines and examples be included as appendices to the minutes. Dr. Young said that the minutes and supplement could be prepared before the next ABRAC meeting, in which case the current ABRAC chair could approve them and a cover letter.

The ABRAC agreed to support the examples with references and to include a list of references at the end of each example.

[Staff note: The guidelines and examples as revised by the ABRAC are published as a supplement to these minutes, Document No. 91-04.]

Dr. Osburn invited Dr. Young to summarize the status of the Biotechnology Research Crosscut.

<u>Summary of Biotechnology Research Crosscut</u>

Dr. Young explained that OSTP had asked all Federal agencies to gather data on biotechnology research, as specified in the Congressional Office of Technology Assessment's 1984 definition. He contrasted the kinds of biotechnology research supported by USDA (basic and applied research) and the kinds of research traditionally performed by the private sector.

Dr. Young indicated that USDA has gathered the necessary data and presented it to OMB for a possible Presidential initiative on biotechnology. He said no decision on such an initiative has been reached, but if the initiative is approved, some USDA biotechnology projects could receive major increases in funding.

Dr. Osburn asked if projects identified by the National Research Initiative (NRI) could receive additional funding. Dr. Young said they could, and added that the NRI had identified 43

biotechnology projects. He noted that of the $99 million in the NRI, about half is devoted to biotechnology products.

Dr. Kline asked about the status of programs to improve the agricultural research work force. Dr. Young responded that much of USDA's effort in this regard focuses on the graduate and post-graduate levels, but that there also are programs to strengthen the 1890 colleges. In addition, ARS has more than 100 postdoctorals, mostly in molecular biology. He said that USDA has only about $20 million to spend on these programs. At the high school level, he said, USDA sponsors the Agriculture in the Classroom program; in addition, 4-H Clubs' science and technology curricula place heavy emphasis on biotechnology.

Dr. Young reminded the ABRAC that the 1990 Food, Agriculture, Conservation, and Trade Act (1990 Farm Bill) stipulates that 1 percent of biotechnology research funding be earmarked for risk assessment. In the biotechnology research inventory, he said, USDA has identified $178.4 million in biotechnology research programs being conducted by the Department. However, he said, the 1990 Farm Bill limits biotechnology to research involving "recombinant" DNA, while USDA's inventory was based on a much broader definition; therefore, the amount of money allocated to risk assessment may be much less than expected.

After a recess for lunch, Dr. Osburn invited Ms. Cordle to update the ABRAC on the Auburn University catfish proposal.

Update on Auburn University Catfish Proposal

Ms. Cordle told the ABRAC that on October 29, 1991, USDA received a request from Auburn University in Alabama to use Hatch Act funding for a confined pond experiment with transgenic catfish offspring. The experimental protocol for the catfish is identical to a previously reviewed protocol for carp, except that twice as many catfish (100,000 fry, of which 50,000 are transgenic) as carp will be used.

Ms. Cordle said she would convene a review team of six fisheries experts to conduct an in-depth review of the experiment. Team members are Meryl Broussard, USDA/CSRS; Charles Brown, USDA/APHIS; Harold Kincaid, U.S. Fish and Wildlife Service; Nick Parker, Texas Tech University; Ernie Brannon, University of Idaho, and Bill Reeves, Alabama Department of Conservation and Natural Resources. She said the proposal will be reviewed at the next ABRAC meeting, at which time the team will present its recommendations.

Following the next ABRAC meeting, according to Ms. Cordle, the CSRS Administrator, will consider recommendations from the fisheries experts and the ABRAC, and decide the best way to

comply with NEPA requirements. The public will have a chance to participate in the decision-making process; in fact, to allow the local community a chance to comment, the next ABRAC meeting could be held near Auburn University instead of in Washington, DC. Dr. Young cautioned that some of the Washington-based groups interested in the research might find it too expensive to attend a meeting in Alabama.

Ms. Cordle said she had received two Freedom of Information Act (FOIA) requests for more information on this experiment, as well as a letter from the National Wildlife Federation asking that the experiment be delayed until the carp experiment was completed.

Dr. Kemp asked if the team would visit the actual site of the experiment. Ms. Cordle replied that a site visit probably would not be necessary.

Dr. Bollinger expressed concern about the cost of building the facility for the experiment. Dr. Young acknowledged that the cost was hundreds of thousands of dollars, perhaps $250,000. Dr. Bollinger asked if the Auburn pond essentially established the standard for ponds elsewhere, or if the evaluation process would have to be repeated for every experiment involving transgenic fish. Dr. Young and Ms. Cordle replied that every effort was being made to prepare a set of standards for contained outdoor ponds so that new standards would not have to be developed for every fish experiment.

Dr. Berkowitz asked if the catfish experiment would result in knowledge that could not be obtained from the carp experiment. Ms. Cordle responded that the researchers had wanted to work with catfish, not carp, in the first place. Catfish is an important aquaculture crop, but the faster maturity rate of carp made the latter species an ideal model. Dr. Kemp noted that carp and catfish do not always behave identically.

Dr. Young said that the National Wildlife Federation and other groups would be invited to the next ABRAC meeting in order to allow those groups to comment on this proposal. He stated that it is very important for these groups and the public to see how and why decisions on such proposals are made.

Dr. Osburn indicated that the ABRAC concurred with the process proposed. He then invited Dr. John Payne to discuss APHIS activities on biotechnology regulation.

Update on APHIS Activities

Dr. Payne said that APHIS biotechnology regulation activities had produced no surprises or big breakthroughs during the past fiscal

year. He directed the ABRAC members to a handout which summarized APHIS activities.

Dr. Young asked whether there are significant differences in the type of work submitted by universities alone, and joint commercial/university activities. Dr. Payne responded that in joint activities, the commercial firm often prepares and submits the application on its own.

Ms. Cordle asked about the status of APHIS efforts to provide guidance on petitions for exemption from regulation. Dr. Payne said that draft guidelines had been sent out for comment, and that applicants had provided considerable feedback. While no one had formally requested an exemption, five or six such requests could come to APHIS within the next few months. He also said that APHIS has never had a specific exemption policy.

Dr. Barbossa asked what percentage of permits were denied after conferring with APHIS. Dr. Payne said that none have been denied, but that two or three out of 211 have been withdrawn. The average turnaround for applications is just over 90 days, he said.

Copies of applications are not circulated unless a request comes under the FOIA. However, the environmental assessments (EA's) APHIS performs on such applications are available to anyone upon request. Dr. Payne said that his staff consists of eight reviewers, and 14 or 15 persons involved with biologics.

Dr. Osburn invited Dr. Marvin Norcross to discuss the activities of USDA's Food Safety and Inspection Service (FSIS) with regard to transgencic animals.

Update on FSIS Activities

Dr. Norcross said that FSIS inspects 130 million red meat animals, 6 billion birds, and 150 billion pounds of processed products every year. Soon, he added, the agency expects to be inspecting transgenic animals, and the agency expects to use the ABRAC's counsel and advice regarding transgenic animals.

Dr. Norcross noted that FSIS is trying to build public support for the use as food of transgenic animals and the non-transgenic offspring of such animals. He referred to a ***Federal Register*** notice specifying the following criteria for determining safety of such animals for use as food: the gene itself; the gene product; other changes in the genome resulting from insertion; and the health of the animal.

Dr. Norcross said that FSIS is striving to take a pro-active approach to dealing with transgenic animals.

Dr. Young asked if the poultry industry would be the first to try to market a transgenic animal. Dr. Norcross replied that commodity groups would be in a better position than he to answer that question. In response to a question from Dr. Vidaver, Dr. Norcross said that the Food and Drug Administration (FDA) and the U.S. Marine Fisheries Service have voluntary programs for fish inspection.

Ms. Cordle inquired about FSIS's definition of "experimental animals." Dr. Norcross replied that this question is being addressed in a public forum, and that he hoped it could be resolved without launching a new regulatory proceeding.

Dr. Osburn invited Dr. Jones to discuss the rechartering of the ABRAC and recruitment of new members.

Rechartering of ABRAC and Recruitment of New Members

Dr. Jones said that the ABRAC must be rechartered every two years. The new draft charter involved mostly changes in the budget for the ABRAC, he said. The draft charter has completed Departmental clearance, and on November 12, 1991, a letter was sent to the General Services Administration explaining why the ABRAC should continue. Following GSA concurrence, he said, the Secretary will review the charter and sign it if he also concurs.

Dr. Jones noted that eight current members of the ABRAC are completing their second terms of service. Two or three nominees have been proposed for each slot, he said, and have been forwarded to the USDA leadership for review. He acknowledged the assistance of professional associations and agency administrators in identifying candidates, and he said a decision on new members is expected in the next month or two.

Dr. Osburn asked Acting Assistant Secretary Harry Mussman to present service awards to the outgoing ABRAC members.

Awards to Outgoing ABRAC Members

Dr. Mussman presented service awards to Dr. Sue Tolin, Dr. Edward Korwek, Dr. John Kemp, Dr. Frank Whitmore, Dr. Ann Sorensen, Dr. Harold Hafs, and Dr. Bennie Osburn. An award also was given to Dr. George Hill, who was not able to attend the meeting.

Other Business and Adjournment

Dr. Young said that the next ABRAC meeting is scheduled for February 19-21, 1992, if the new charter is approved and new

members appointed. He said a second meeting was likely during the second week of June.

Dr. Young mentioned some upcoming meetings of interest to ABRAC members, including a Workshop on Communication in biotechnology to be held in Dublin in March, 1992, and a followup to the Kiawah Island symposium to be held in Gosler, Germany, in May, 1992. Dr. Young said he would explore whether USDA could send the new ABRAC chairman to the Gosler symposium.

Dr. Jones said that a European publication, ***Agricultural Ecosystems and the Environment***, expressed interest in publishing a brief summary of the Guidelines. Dr. Tolin said that a U.S. journal on issues in science and technology also might be interested.

Dr. Mussman observed that once the Guidelines are published in the ***Federal Register***, all of the scientific journals would want to write summaries themselves. Dr. Hafs explained that the ABRAC is concerned that the Guidelines might never be published in the ***Federal Register.*** Dr. Mussman said that it was in USDA's best interest to publish the Guidelines.

Dr. Osburn thanked the OAB staff and Dr. Young for its support of the ABRAC, and expressed appreciation for the support of the Assistant Secretary, Ms. Zannoni, and Dr. MacKenzie. He also thanked the liaison groups and their representatives, as well as visitors to the meeting. Dr. Tolin thanked Dr. Osburn for his leadership of the ABRAC over the past four years.

Dr. Osburn adjourned the meeting at 2:45 p.m.

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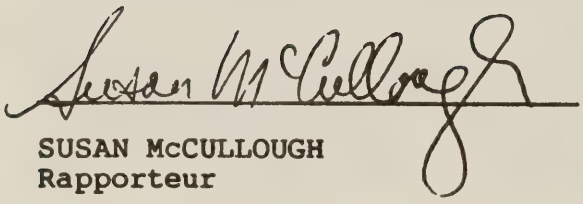
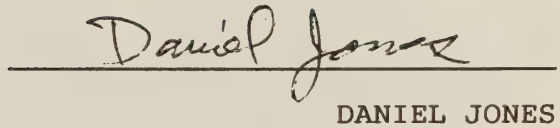
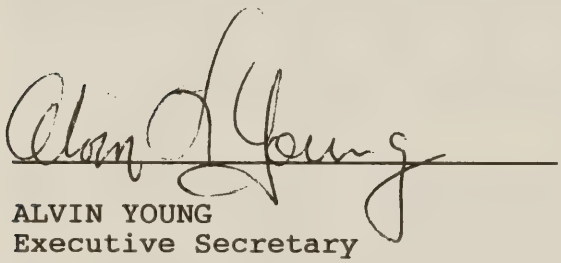
Approved:



SUSAN McCULLOUGH
Rapporteur



DANIEL JONES
Editor



ALVIN YOUNG
Executive Secretary

BENNIE OSBURN
Chair

APPENDIX A

LIST OF VISITORS
UNITED STATES DEPARTMENT OF AGRICULTURE
AGRICULTURAL BIOTECHNOLOGY RESEARCH ADVISORY COMMITTEE
Meeting of December 3-4, 1991

Pedro Barbossa, University of Maryland
Robert Warmbrodt, USDA National Agricultural Library
David Berkowitz, U.S. Food and Drug Administration
Fred Blosser, Bureau of National Affairs
Larry McDaniel, American Type Culture Collection
Bruce Umminger, National Science Foundation
Michael Fernandez, Senate Agriculture Committee
Kent Reed, ***Food Chemical News***
Mary Stangeland, USDA Office of the Consumer Advisor
Kris Herbst, ***BioWorld***
Janet Shoemaker, American Society for Microbiology
Robert Zimbelman, American Society of Animal Science
Oto Urban, USDA Food Safety and Inspection Service
Pat Basu, USDA Food Safety and Inspection Service
Bharat Patel, USDA Food Safety and Inspection Service
Diane Jaeng, U.S. Food and Drug Administration
Lisa Zannoni, USDA Office of the Secretary
Debbie Olson, SRI International
Jay Blowers, USDA Cooperative State Research Service
Margriet Caswell, USDA Economic Research Service
Marvin Norcross, USDA Food Safety and Inspection Service
David MacKenzie, USDA Cooperative State Research Service
Michael Schechtman, USDA Animal and Plant Health Inspection Service
John Payne, USDA Animal and Plant Health Inspection Service
Maury Silverman
John Willis

* U.S. G.P.O.:1992-311-403:60029/CSRS